

## ARTICLE 1. ADMINISTRATION

### R4-23-110. Definitions

In addition to definitions in A.R.S. § 32-1901, the following definitions apply to 4 A.A.C. 23:

"AHCCCS" means the Arizona Health Care Cost Containment System.

"Annual family income" means the combined yearly gross earned income and unearned income of all adult individuals within a family unit.

"Earned income" means monetary payments received by an individual as a result of work performed or rental property owned or leased by the individual, including:

Wages,

Commissions and fees,

Salaries and tips,

Profit from self-employment,

Profit from rent received from a tenant or boarder, and

Any other monetary payments received by an individual for work performed or rental of property.

"Family unit" means:

A group of individuals residing together who are related by birth, marriage, or adoption; or

An individual who:

Does not reside with another individual; or

Resides only with another individual or group of individuals to whom the individual is unrelated by birth, marriage, or adoption.

"Health care decision maker" has the same meaning as in A.R.S. § 12-2291.

"Health care institution" has the same meaning as in A.R.S. § 36-401.

"Licensed health care professional" means a individual who is licensed and regulated under A.R.S. Title 32, Chapter 7, 11, 13, 14, 15, 16, 17, 18, 25, 29, or 35.

"Low-income subsidy" means Medicare-provided assistance that may partially or fully cover the costs of drugs and is based on the income of an individual and, if applicable, the individual's spouse.

"Medicare" means a federal health insurance program established under Title XVIII of the Social Security Act.

"Physician" means a medical practitioner licensed under A.R.S. Title 32, Chapter 13 or 17.

"Physician-in-charge" means a physician who is responsible to the Board for all aspects of a prescription medication donation program prescribed in A.R.S. § 32-1909 and operated in the physician's office or in a health care institution.

"Poverty level" means the annual family income for a family unit of a particular size, as specified in the poverty guidelines updated annually in the Federal Register by the U.S. Department of Health and Human Services.

"Primary care provider" means the medical practitioner who is treating an individual for a disease or medical condition.

"Resident" means:

~~a person~~ An individual admitted to and ~~residing~~ living in a long-term care facility,

An individual who has a place of habitation in Arizona and lives in Arizona as other than a tourist, or

A person who owns or operates a place of business in Arizona.

"Tourist" means an individual who is living in Arizona but maintains a place of habitation outside of Arizona and lives outside of Arizona for more than six months during a calendar year.

"Unearned income" means monetary payment received by an individual that are not compensation for work performed or rental of property owned or leased by the individual, including:

Unemployment insurance;

Workers' compensation;

Disability payments;

Payments from the Social Security Administration;

Payments from public assistance;

Periodic insurance or annuity payments;

Retirement or pension payments;

Strike benefits from union funds;

Training stipends;

Child support payments;

Alimony payments;

Military family allotments;

Regular support payments from a relative or other individual not residing in the household;

Investment income;

Royalty payments;

Periodic payments from estates or trusts, and

Any other monetary payments received by an individual that are not:

As a result of work performed or rental of property owned by the individual,

Gifts,

Lump-sum capital gains payments,

Lump-sum inheritance payments,

Lump-sum insurance payments, or

Payments made to compensate for person injury.

"Veteran" means an individual who has served in the United States Armed Forces.

## **ARTICLE 12. PRESCRIPTION MEDICATION DONATION PROGRAM**

### **R4-23-1201. Eligibility Requirements for Participation in the Program**

A physician's office, a pharmacy, or a health care institution may participate in the prescription medication donation program, under A.R.S. § 32-1909, if all of the following requirements, as applicable, are met:

1. The physician-in-charge of the participating physician's office has a current license issued under A.R.S. Title 32, Chapter 13 or 17;
2. The pharmacy has a current permit issued under A.R.S. Title 32, Chapter 18;
3. The health care institution has a current license issued under A.R.S. Title 36, Chapter 4 and has a physician-in-charge or pharmacist-in-charge of dispensing; and

4. The physician's office, the pharmacy, or the health care institution complies with all federal and state drug laws, rules, and regulations.

**R4-23-1202. Donating Medications**

**A.** The following may donate an eligible prescription medication, as specified in R4-23-1203, to a physician's office, a pharmacy, or a health care institution that participates in the prescription medication donation program:

1. An individual for whom the prescription medication was prescribed on a patient-specific prescription order or that individual's health care decision maker;
2. A manufacturer that has a current permit issued under A.R.S. Title 32, Chapter 18; or
3. A health care institution that has a current license issued under A.R.S. Title 36, Chapter 4.

**B.** An individual or health care decision maker electing to donate an eligible prescription medication shall not have taken possession of the prescription medication before the donation and shall make the donation through a medical practitioner, pharmacy, or health care institution.

**R4-23-1203. Eligible Prescription Medications**

A prescription medication may be donated to a physician's office, a pharmacy, or a health care institution that participates in the prescription medication donation program if the prescription medication:

1. Is not a:
  - a. Controlled substance;
  - b. Drug sample; or

- c. Drug that can only be dispensed to a patient registered with the drug's manufacturer, because donation could prevent the manufacturer from maintaining required patient registration data;
- 2. Is in its original sealed and tamper-evident unit dose packaging that is unopened or has only its outside packaging opened and its single unit dose packaging undisturbed;
- 3. Has been in the possession of a licensed health care professional, manufacturer, pharmacy, or health care institution and not in the possession of the individual specified in R4-23-1202(A)(1);
- 4. Has been stored according to federal and state drug law and the requirements of the manufacturer's package insert;
- 5. Has an expiration date or beyond-use-date later than six months after the date of donation;
- 6. Is in packaging that shows the lot number and expiration date or beyond-use-date of the prescription medication;
- 7. Does not have any physical signs of tampering or adulteration; and
- 8. Is in packaging that does not have any physical signs of tampering, except for the outside packaging as specified in subsection (2).

**R4-23-1204. Eligibility Requirements to Receive Donated Prescription Medications**

An individual is eligible to receive donated prescription medications from the prescription medication donation program if the individual:

- 1. Is a resident of Arizona;
- 2. Has an annual family income that is less than or equal to 300% of the poverty level;
- 3. Satisfies one of the following:

- a. Has no health insurance coverage;
- b. Has health insurance coverage that does not pay for the prescription medication prescribed;
- c. Is an American or Alaska Native who:
  - i. Is eligible for, but chooses not to use, the Indian Health Service to receive prescription medications; and
  - ii. Either has no other health insurance coverage or has health insurance coverage that does not pay for the prescription medication prescribed; or
- d. Is a veteran who:
  - i. Is eligible for, but chooses not to use, Veterans Health Administration benefits to receive prescription medications; and
  - ii. Either has no other health insurance coverage or has health insurance coverage that does not pay for the prescription medication prescribed;
- 4. Is ineligible for enrollment in AHCCCS; and
- 5. If eligible for Medicare, is ineligible for a full low-income subsidy.

**R4-23-1205. Donor Form**

- A.** Before donating a prescription medication, a donor shall sign a form that includes:
- 1. A statement attesting that the donor is one of the entities identified in R4-23-1202(A) and intends to voluntarily donate the prescription medication to the prescription medication donation program;
  - 2. If the donor is the individual named on the prescription or the individual's health care decision maker:
    - a. The individual's name and address;

- b. The name of the individual's health care decision maker, if applicable;
- c. The name of the medical practitioner, pharmacy, or health care institution through which the donation is being made;
- d. The following information about the donated prescription medication:
  - i. The brand name or generic name of the prescription medication donated;
  - ii. If a generic medication, the name of the manufacturer or the national drug code number of the prescription medication donated;
  - iii. The strength of the prescription medication donated;
  - iv. The quantity of the prescription medication donated;
  - v. The lot number of the prescription medication donated; and
  - vi. The expiration date or beyond-use-date of the prescription medication donated;
- e. A statement attesting that the individual or the individual's health care decision maker has not had possession of the donated prescription medication;
- f. The dated signature of the individual or the individual's health care decision maker;
- g. If the donation is an ongoing donation as authorized under subsection (B), a statement that conforms to subsection (B);
- h. A statement by the medical practitioner, pharmacy, or health care institution attesting that the medical practitioner, pharmacy, or health care institution through which the donation is being made has stored the donated prescription medication as required in R4-23-1203(4); and

- i. The dated signature of the medical practitioner or of an authorized agent for the pharmacy or health care institution through which the donation is being made;
  3. If the donor is a manufacturer:
    - a. The name and address of the manufacturer;
    - b. The information about the donated prescription medication specified in subsection (A)(2)(d);
    - c. A statement by the manufacturer that the manufacturer has stored the donated prescription medication as required in R4-23-1203(4); and
    - d. The dated signature of the manufacturer's authorized agent; and
  4. If the donor is a health care institution:
    - a. The name and address of the health care institution;
    - b. The information about the donated prescription medication specified in subsection (A)(2)(d);
    - c. A statement attesting that the health care institution has stored the donated prescription medication as required in R4-23-1203(4); and
    - d. The dated signature of the health care institution's authorized agent.
- B.** An individual who resides in a health care institution, or the individual's health care decision maker, may elect to make an ongoing donation of future unused eligible prescription medication:
1. When future unused eligible prescription medication is a result of the individual's prescription medication being changed or discontinued by the individual's primary care provider; and



2. By indicating the following on a donor form that complies with subsection (A):  
“From this day forward, I wish to donate all my remaining unused prescription  
medications that are eligible, under R4-23-1203, to the prescription medication  
donation program.”

**C.** To stop an ongoing donation, an individual who resides in a health care institution, or the  
individual's health care decision maker, shall submit written notice to the receiving  
physician's office, pharmacy, or health care institution indicating the individual's, or the  
health care decision maker's, desire to stop the ongoing donation.

**R4-23-1206. Recipient Form**

Before receiving a donated prescription medication from the prescription medication donation  
program, a recipient of a donated prescription medication shall sign a form:

1. Identifying the physician's office, pharmacy, or health care institution that is  
dispensing the donated prescription medication;
2. Stating that the recipient understands the immunity provisions of the program under  
A.R.S. § 32-1909(E) and (F);
3. Attesting that the recipient meets the eligibility requirements specified in R4-23-1204:  
and
4. Including the following:
  - a. The brand name or generic name of the prescription medication received;
  - b. If a generic medication, the name of the manufacturer or the national drug code  
number of the prescription medication received;
  - c. The strength of the prescription medication received;
  - d. The quantity of the prescription medication received;

- e. The recipient's name and address; and
- f. The dated signature of the recipient.

**R4-23-1207. Recordkeeping**

**A.** Before transferring possession of a prescription medication donated by an individual or an individual's health care decision maker, a medical practitioner, pharmacy, or health care institution that has possession of the donated prescription medication and through which the donation is being made shall create an invoice that includes the following:

1. The name and address of the medical practitioner, pharmacy, or health care institution that has possession of the donated prescription medication;
2. The name of the individual who made the donation;
3. The brand name or generic name of the prescription medication transferred;
4. If a generic medication, the name of the manufacturer or the national drug code number of the prescription medication transferred;
5. The strength of the prescription medication transferred;
6. The quantity of the prescription medication transferred;
7. The lot number of the prescription medication transferred;
8. The expiration date or beyond-use-date of the prescription medication transferred;
9. The date the prescription medication is transferred to a participating physician's office, pharmacy, or health care institution; and
10. The name and address of the participating physician's office, pharmacy, or health care institution to which the donated prescription medication is transferred.

- B.** Before transferring possession of a prescription medication donated by a manufacturer, the manufacturer shall create an invoice that includes the manufacturer's name and address and the information described in subsections (A)(3) through (10).
- C.** Before transferring possession of a prescription medication donated by a health care institution, the health care institution shall create an invoice that includes the health care institution's name and address and the information described in subsections (A)(3) through (10).
- D.** A medical practitioner, pharmacy, health care institution, or manufacturer required to create an invoice under subsection (A), (B), or (C) shall:
1. Transmit a copy of the invoice and the donor form required under R4-23-1205 to the participating physician's office, pharmacy, or health care institution to which a donated prescription medication is transferred;
  2. Maintain a copy of the invoice for a minimum of three years from the date of the invoice;
  3. Maintain a copy of the donor form for a minimum of three years from the date signed; and
  4. Make a copy of the invoice or donor form available upon request for inspection by the Board, its designee, or other authorized officers of the law.
- E.** A physician's office, a pharmacy, or a health care institution that participates in the prescription medication donation program shall:
1. Maintain:
    - a. The documents required under R4-23-1206 for a minimum of three years from the date signed; and

- b. Each invoice and donor form received under subsection (D)(1) for a minimum of three years from the date received; and
2. Make the documents required under R4-23-1206 and subsection (D)(1) available upon request for inspection by the Board, its designee, or other authorized officers of the law.

**R4-23-1208. Handling Fee**

A physician's office, a pharmacy, or a health care institution that dispenses a donated prescription medication may charge a recipient of a donated prescription medication a handling fee of no more than \$4.50 per prescription to cover inspection, stocking, and dispensing costs.

**R4-23-1209. Policies and Procedures**

A physician's office, a pharmacy, or a health care institution that participates in the prescription medication donation program shall:

1. Develop, implement, and comply with policies and procedures for the receipt, storage, and distribution of prescription medications donated to the physician's office, the pharmacy, or the health care institution;
2. Review biennially and, if necessary, revise the policies and procedures required under this Section;
3. Document the review required under subsection (2);
4. Assemble the policies and procedures as a written manual or in a readily accessible electronic format;
5. Make the policies and procedures available for reference by physician's office, pharmacy, or health care institution personnel and, upon request, for inspection by the Board or its designee; and

6. Ensure that the written or electronic policies and procedures required under subsection (1) include provisions to ensure:
  - a. That each transferred prescription medication meets the eligibility requirements of Sections R4-23-1202 and R4-23-1203;
  - b. That each individual who receives a donated prescription medication under the prescription medication donation program signs the recipient form specified in R4-23-1206;
  - c. Compliance with the applicable requirements for recordkeeping in Section R4-23-1207;
  - d. Compliance with the requirements of Section R4-23-1210; and
  - e. Compliance with the requirements of Section R4-23-1211.

**R4-23-1210. Dispensing Donated Prescription Medications**

- A.** Before dispensing a donated prescription medication under the program, a participating physician's office, pharmacy, or health care institution shall:
1. Obtain and maintain a current drug identification reference or text in hard-copy or electronic media format;
  2. Inspect the donated prescription medication to ensure that the prescription medication has not been adulterated;
  3. Certify that the donated prescription medication has been stored in compliance with the requirements of the manufacturer's package insert;
  4. Comply with all federal and state laws regarding storage and distribution of a donated prescription medication;

5. Obtain a prescription order of a licensed medical practitioner for the recipient to receive the donated prescription medication; and
  6. Properly label the donated prescription medication to be dispensed.
- B.** As specified in subsection (C) a participating physician's office, pharmacy, or health care institution may transfer a prescription medication donated under this Article to another participating physician's office, pharmacy, or health care institution, but the donated prescription medication shall not be resold.
- C.** A participating physician's office, pharmacy, or health care institution may transfer a donated prescription medication to another participating physician's office, pharmacy, or health care institution, if:
1. The transferring physician's office, pharmacy, or health care institution has available a prescription medication that the receiving physician's office, pharmacy, or health care institution needs;
  2. The transferring physician's office, pharmacy, or health care institution prepares an invoice that includes its name and address and the information described in R4-23-1207(B)(3) through (10);
  3. A copy of the invoice required in subsection (C)(2) is sent to the receiving physician's office, pharmacy, or health care institution with the transferred prescription medication; and
  4. The transferring physician's office, pharmacy, or health care institution and the receiving physician's office, pharmacy, or health care institution each:
    - a. Keep a copy of the invoice required in subsection (C)(2) on file for three years from the date of transfer; and

- b. Make the invoice records available, upon request, for inspection by the Board or its designee.

**R4-23-1211. Responsibilities of the Physician or Pharmacist-in-charge of a Participating Physician's Office, Pharmacy, or Health Care Institution**

The physician-in-charge of a participating physician's office; the pharmacist-in-charge of a participating pharmacy; or the physician-in-charge or pharmacist-in-charge of dispensing for a participating health care institution shall, either personally or through a designee:

1. Coordinate the receipt of prescription medications donated by manufacturers or health care institutions or through medical practitioners, pharmacies, or health care institutions from eligible donors;
2. Check each donated prescription medication against the invoice and any additional alternate record and resolve any discrepancies;
3. Store and secure donated prescription medications as required by federal and state law;
4. Inspect each donated prescription medication for adulteration;
5. Certify that each donated prescription medication has been stored in compliance with the manufacturer's package insert;
6. Ensure that expired, adulterated, or unidentifiable donated prescription medication is not dispensed;
7. Ensure that prescription medications identified under subsection (6) are destroyed within 30 days of identification as specified in subsection (9);
8. Ensure safety in drug recalls by destroying any donated prescription medication that may be subject to recall if its lot number cannot exclude it from recall;

9. Ensure destruction of expired, adulterated, unidentifiable, and recalled donated prescription medication by:
  - a. Following federal, state, and local guidelines for drug destruction;
  - b. Creating a list of expired, adulterated, unidentifiable, or recalled donated prescription medications to be destroyed;
  - c. Following the destruction, signing the list described in subsection (9)(b) and having the list signed by a witness verifying the destruction; and
  - d. Keeping the list described in subsection (9)(b) on file for three years from the date of destruction;
10. Redact or remove all previous patient or pharmacy labeling on a donated prescription medication before dispensing the donated prescription medication;
11. Ensure that all dispensed donated prescription medications comply with the labeling requirements of A.R.S. § 32-1968(D);
12. Place on the label of each dispensed donated prescription medication a beyond-use-date that does not exceed the beyond-use-date or expiration date from the original label of the donated prescription medication or, if the dispensed donated prescription medication comes from multiple packages, the earliest beyond-use-date or expiration date from the donated prescription medication packages; and
13. Maintain the records required in this Article.